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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,858	SEIM ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 16 October 2006 have been fully considered but they are not persuasive. Examiner respectfully disagrees with all of Applicant's arguments regarding the 35 USC § 112 second paragraph rejections except the one regarding claim 60 which has been corrected. For all of Applicant's other arguments for these rejections, Applicant argued that Applicant's Specification provides further support for understanding the claims and resolving the Examiner's stated concerns, and Applicant subsequently pointed to portions of the specification for discussions about the rejected terms. A reading of the specification provides no evidence to indicate that these limitations must be imported into the claims to give meaning to the disputed terms. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Consequently, Examiner maintains claims 36–60 rejected under 35 USC § 112 second paragraph as set forth in the Office Action mailed on 12 July 2006 and re-submitted herein below. It is noted that claim 60 remains rejected under 35 USC § 112 second paragraph because it depends from claim 55 which depends from rejected claim 36.

2. Examiner respectfully disagrees with Applicant's arguments that Levine fails to teach or contemplate disabling ATP therapy for any reason and that Levine clearly fails to teach disabling ATP therapy in response to a measured impedance deviating from a threshold. In light of the broadest interpretation of the claimed limitation, it is the Examiner's position that Levine disables ATP as taught in column 11, lines 11–20 when therapy is switched from one electrode

configuration (for illustration purposes I will call this configuration A) to a different electrode configuration (configuration B), therapy is disabled on configuration A. Applicant did not claim disabling atrial ATP therapy delivery and not applying therapy elsewhere after the therapy is disable. Applicant further pointed to a substantial portion of the specification for discussions about independent claims 1, 20, 36, 61 and 62 clearly being distinguishable over the Levine reference when viewed in light of Applicant's Specification. A reading of the specification provides no evidence to indicate that these limitations must be imported into the claims to give meaning to the disputed terms. Applicant misinterprets the principle that claims are interpreted in the light of the specification. Although these elements are found as examples or embodiments in the secification, they were not claimed explicitly. Nor were the words that are used in the claims definded in the specification to require these limitations.

3. In response to Applicant's argument that these customizable parameters specified by Levine only include parameters for detecting arrhythmia and delivery of a therapy (i.e. pulse amplitude, duration, rate, etc.) and do not include an impedance threshold developed for a particular patient, Examiner respectfully disagrees. In the section pointed to by the Examiner (and re-stated by the Applicant) in support of the limitation of an impedance threshold developed for a particular patient (e.g., column 11, lines 11–15 and column 8, line 65–column 9, line 7), Levine meets this claimed limitation because included in the list of parameters that are developed for the particular patient is electrode polarity which is directly related to the characteristic of an impedance threshold and plays an integral part when measuring impedance as disclosed in the sections cited above and as set forth in said claimed limitation.

4. Regarding Applicant's argument that Levine does not teach measuring a sense amplitude, nor does Levine teach comparing a capture threshold with a capture threshold limit or comparing a sense amplitude measurement with a sense amplitude limit, Examiner respectfully disagrees. Applicant pointed to sections in Levine that Examiner did not cite to show the claimed limitations set forth herein. Not only do the sections pointed to by the Examiner read on said claimed limitations (e.g., column 7, lines 59 and 65; column 10, lines 12–13 and 28–30 and column 10, lines 35–55), but, it is inherent that the device, and many like it in the art, inherently perform the said claimed limitations because sense amplifiers coupled with leads and all other associated circuitry of the device have to perform various comparisons and threshold checks on a consistent and regular basis in order to negotiate and execute the various functions and therapies that the device provides.

5. Consequently, Examiner maintains both claim rejections 35 U.S.C. § 102(e) as being anticipated by Levine et al., U.S. Patent 7,031,773 for claims 1–3, 10–19, 20, 24–27, 36–39, 44–55 and 59–62 and 35 U.S.C. § 103(a) as being unpatentable over Levine et al., U.S. Patent 7,031,773 for claims 4–8, 21–23, 28–29, 40–43 and 56–58 as set forth in said Office Action and as re-submitted herein below. The 35 U.S.C. § 103(a) claim rejection is being maintained in light of the claims' dependency on the rejection of their respective independent claims that has been maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 36–60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 36, the phrase "coupled to memory" is inferentially included and vague. It is unclear if the memory is being positively recited or functionally recited. To positively claim element, it is suggested to first positively recite the element. Otherwise functional language such as "for" or "adapted to be" should be used. Additionally, the phrase "the control system disabling atrial ATP therapy" is likewise inferentially included and vague. It is unknown which element provides the atrial ATP therapy.

In claims 37–39, the phrases "the impedance threshold ... lead impedance measurement" are vague. It is unclear what element is performing this function in each claim.

In claims 40–41, the phrases "the impedance threshold ... measured impedance" are vague. It is unclear what element is performing this function in each claim.

In claims 46–48, the phrases "the predetermined factor ... the impedance threshold" are vague. It is unclear what element is performing this function in each claim.

In claim 49, the phrase "a pace pulse" is inferentially included and vague. It is unclear what element is providing a pace pulse.

In claim 50, the phrase "a stimulus delivered" is inferentially included and vague. It is unclear what element is providing a stimulus.

In claim 51, the phrase "after detection of an atrial arrhythmic event" is vague. It is unclear what element is providing detection of an atrial arrhythmic event.

In claim 52, the phrase "after an atrial arrhythmic episode" is vague. It is unclear what element is providing an atrial arrhythmic episode.

In claim 53, the phrase "after detection of an atrial arrhythmic event" is vague. It is unclear what element is providing detection of an atrial arrhythmic event.

In claim 54, the phrase "after an atrial arrhythmic episode" is vague. It is unclear what element is providing an atrial arrhythmic episode.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1–3, 10–19, 20, 24–27, 36–39, 44–55 and 59–62 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine et al., U.S. Patent 7,031,773.

10. Regarding claims 1, 20, 36, 55, 61, and 62, (NOTE: Only the differing limitation of each claim will be indicated parenthetically; the common limitations will not be.) Levine et al. disclose measuring an impedance of an atrial lead (e.g., column 11, lines 5 and 7–10; column 13, lines 52–53; column 14, lines 21–23); comparing a measured impedance with an impedance threshold developed for a particular patient (e.g., column 11, lines 11–15; column 8, last line–column 9, lines 1–2; column 13, lines 59–60); disabling atrial ATP therapy delivery in response to a measured impedance deviating from an impedance threshold by a predetermined factor (e.g., column 11, lines 11–19 wherein the step of switching the electrode configuration to an electrode configuration other than the current electrode configuration represents disabling atrial ATP therapy delivery to the electrode configuration previously receiving the therapy); measuring a

capture threshold (e.g., column 12, lines 26–28), and a sense amplitude (evoked response) (e.g., column 7, lines 59 and 65; column 10, lines 12–13 and 28–30) (claims 20, 55, and 62); comparing capture threshold, and sense amplitude measurements with capture threshold, and sense amplitude limits, respectively (e.g., column 10, lines 35–55) (claims 20, 55, and 62); an implantable housing (e.g., Fig. 1); detection circuitry (e.g., Fig. 2); energy delivery circuitry (e.g., Fig. 2); a lead system respectively coupled to a detection and energy delivery circuitry, a lead system comprising at least an atrial lead (e.g., Figs. 1–2) and a control system provided in a housing and coupled to memory within which an impedance threshold developed for a particular patient is stored (e.g., Fig. 2) (claim 36).

11. Levine et al. disclose an impedance threshold is developed from a single atrial lead impedance measurement (claims 2, 26, and 37) and a plurality of atrial lead impedance measurements (claims 3, 27 and 38) (e.g., Fig. 3; column 11, lines 11–15); wherein measuring an impedance of an atrial lead comprises taking a plurality of impedance measurements to characterize an impedance of an atrial lead (claims 9 and 44) (e.g., Fig. 3, elements 208 and 220); measuring an impedance of an atrial lead comprises taking a single impedance measurement to characterize an impedance of an atrial lead (claims 10 and 45) (e.g., column 13, lines 52–53); a predetermined factor is characterized by a percentage change in a measured impedance relative to an impedance threshold (claims 11 and 46) (e.g., column 11, lines 10–15) and a fixed delta change (500 ohms) in the measured impedance relative to the impedance threshold (claims 12 and 47) (e.g., column 11, lines 13–14) and both a percentage change and a fixed delta change in the measured impedance relative to the impedance threshold (claims 13 and 48) (e.g., column 11, lines 10–15 and 13–14); measuring an impedance comprises delivering a

pace pulse via an atrial lead and deriving an impedance measurement using a delivered pace pulse (claims 14 and 49) (e.g., Fig. 3; column 12, lines 7–14) and using a delivered stimulus, a stimulus having an energy insufficient to effect atrial capture (claims 15 and 50) (e.g., Fig. 3; column 12, lines 22–30); an impedance is measured after detection of an atrial arrhythmic event and prior to atrial ATP therapy delivery (claims 16 and 51) (e.g., Fig. 3; column 12, lines 9–25); an impedance is measured after an atrial arrhythmic episode is declared and prior to atrial ATP therapy delivery (claims 17 and 52) (e.g., Fig. 3; column 12, lines 31–37); measuring an impedance comprises taking a plurality of impedance measurements after detection of an atrial arrhythmic event (claims 18 and 53) and after an atrial arrhythmic episode is declared (claims 19 and 54) and prior to atrial ATP therapy delivery (e.g., Fig. 3; column 12, lines 9–25); disabling ATP therapy delivery comprises, upon detection of an atrial arrhythmia, ignoring a capture threshold and sense amplitude deviations (claims 25 and 60), and disabling ATP therapy in response only to the measured impedance deviating from the impedance limit by the predetermined factor (claims 24, 25, 59, and 60) (e.g., Fig. 3; column 12, lines 31–37); an impedance threshold is capable of being characterized by a mean or a median of a plurality of atrial lead impedance measurements (claim 39) because a variance from a previous measurement by some other suitable value (e.g., as shown in column 12 lines 18–21), for example, a mean or median value, is commonly used in an impedance measurement system to measure lead impedance.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 4–8, 21–23, 28–29, 40–43, and 56–58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al., U.S. Patent 7,031,773.

15. Levine et al. disclose the essential features of the claimed invention as discussed above except for an impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements (claims 4 and 39) and by an atrial lead impedance measurement taken immediately before a currently measured impedance (claims 5, 28 and 40) and at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement (claims 6, 29, and 41); and a predetermined amount of time is about one day (claims 7 and 42) and more than one day (claims 8 and 42). However, it is well known in the art to characterize an impedance threshold as set forth in the claim limitations stated herein because they indicate relative displacement of the implanted cardiac lead giving the physician viable information to initiate definitive therapy at the appropriate time. Therefore, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Levine et al. to include an impedance threshold is characterized by a mean or a median of a plurality of atrial lead impedance measurements and by an atrial lead impedance measurement taken immediately before a currently measured impedance and at least one atrial lead impedance measurement taken a predetermined amount of time prior to the impedance measurement; and a predetermined amount of time is about one day and more than one day to provide a device that allows for delivery of optimal and efficient therapy in a timely manner.

16. Regarding claims 21–23 and 56–58, Levine et al. disclose the claimed invention as discussed in claims 20 and 24–25 above but does not disclose expressly detecting an ambiguity in the impedance, capture threshold, and sense amplitude deviations. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the impedance, capture threshold, and sense amplitude as taught by Levine et al. (e.g., as discussed in the rejection for claims 20 and 24–25 above), to detect an ambiguity, because Applicant has not disclosed that detecting an ambiguity provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the impedance, capture threshold, and sense amplitude as taught by Levine et al., because they indicate relative displacement of the implanted cardiac lead giving the physician viable information to initiate definitive therapy at the appropriate time and provide a device that allows for delivery of optimal and efficient therapy in a timely manner. Therefore, it would have been an obvious matter of engineering design choice to modify the impedance, capture threshold, and sense amplitude to obtain the invention as specified in the claims.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
May 23, 2007
23 May 2007

GEORGE R. EVANISKO
PRIMARY EXAMINER
5/24/7